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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/461,402	06/05/1995	ANDREW H. CRAGG	94-P0273US02	6448

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EXAMINER	
SONNETT, KATHLEEN C	
ART UNIT	PAPER NUMBER
3731	

MAIL DATE	DELIVERY MODE
12/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	08/461,402	CRAGG ET AL.	
	Examiner	Art Unit	
	KATHLEEN SONNETT	3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *96-106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *96-106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/20/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/20/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. **Claims 96-99 and 101-103** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 5,575,817) in view of Hillstead (US 4,856,516) and Cottone, Jr. (US 5,549,663; "Cottone"). Martin discloses an apparatus for reinforcing a bifurcated lumen comprising a proximal stent (1) having a proximal and distal end, the proximal stent further having a proximal orifice at the proximal end to be located in and when expanded to be supported by a vascular vessel, at least one distal stent (2) having a proximal and distal end. The proximal stent has two transversely placed tapering portions that extend from an intermediate portion to the distal end of the proximal stent to reinforce the bifurcated lumen. In particular, note that the sections near reference numbers 1 and 5 in fig. 4 are tapered. These sections extend to the distal end of the proximal stent. The proximal stent has a distal orifice at the distal end of at least one of the tapering portions which, when expanded, serves to receive the proximal end of the at least one

distal stent. The proximal stent and the at least one distal stent each comprise an expandable stent constructed with a wire skeleton having one or more parts that extends from the proximal to the distal ends. The cross sectional area (CSA) of the proximal end of the distal stent (2) is larger than the CSA of the distal orifice of the proximal stent so as to partially secure together the stents when the distal stent is expanded within the proximal stent (col. 3, ll. 29-36). Martin fails to disclose the claimed structure of the stent regarding the hoops comprising a sinuous wire.

4. Hillstead teaches constructing a stent such that it comprises a plurality of hoops which are axially displaced in a tubular configuration along a common axis, each of the hoops being formed by a substantially complete turn of a sinuous wire having apices and having a circumference that lies in a plane substantially perpendicular to the longitudinal axis of the stent. It would have been obvious to incorporate this stent structure into the stents of Martin in order to gain the advantages associated with this structure including a high degree of flexibility and a more direct and uniform application of expansion forces to the stent (see entire document, esp. col. 2, ll. 14-25). Hillstead fails to disclose that the apices of adjacent hoops are juxtaposed to one another and at least two juxtaposed apices are connected by a securing means. Cottone teaches providing wire hoops which are out of phase such that apices of adjacent hoops are juxtaposed to one another and are connected by a securing means (weld point 18). These securing means are advantageous because, when applied at least to end portions of the stent, they provide anchoring portions within the stent which possess greater hoop strength than un-welded end portions, thereby making less likely unintentional movement of the stent after deployment (col. 1, ll. 20-24; col. 4, ll. 48-64). It would have been obvious to incorporate such a securing means as taught by Cottone into the device of Martin in view of HIllstead so that it too may have this advantage.

5. Regarding claims 97 and 98, the proximal stent of Martin can be considered to have two intermediate portions, each of which are tapered to form distal portions with distal orifices. One of these tapered portions can be considered the relatively short inclined extension that enables the distal stent to be located therein and secured thereto when the short extension has been expanded.

6. Regarding claim 99, see platinum wire (12).

7. Regarding claim 101, the proximal and distal stents are configured for placement at a bifurcation. The proximal stent includes a lumen (within 5) that is configured to be disposed entirely within the vessel and is adapted to secure to the distal stent configured to extend into one of the two branched vessels.

8. Regarding claim 102, in figure 4 of Martin, the proximal portion of distal stent (2) and the distal portion (5) of proximal stent (1) are both tapered and cylindrical and therefore form frustoconical shapes. Martin discloses that the proximal portion of distal stent (2) interference fits within distal portion (5) and therefore the distal stent includes a frustoconically shaped male engaging portion and the proximal stent includes a frustoconically shaped female engaging portion. Martin further teaches that these portions form an interference fit and therefore the portions engage each other to resist longitudinal movement. Each of these portions comprises a stent made of a wire skeleton since the entire device is made from such a skeleton covered with graft material.

9. Regarding claim 103, the distal stent has a fabric layer covering its outer surface. Since the proximal end of the distal stent is placed within the distal end of the proximal stent, the fabric layer will be between the male and female portions. This will form a substantially fluid-tight seal since the male and female portions are interference fit.

10. **Claim 100** is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin '817 in view of Hillstead and Cottone as applied to claim 96 above and further in view of Liebig (US 3,805,301). Martin '817 in view of Hillstead and Cottone discloses the invention substantially as stated above including radiographic indicia on the proximal and distal stents (wire 12). The wire of Martin '817 goes around the entire circumference of the stents and therefore the image of the radiopaque markers will not vary with the rotational orientation of the stent. However, Liebig teaches that it is well known to provide markers along the longitudinal axis of a stent such that the rotational orientation affects the shape of the marker. In particular, if the graft is twisted at all, the marker will be twisted. It would have been obvious to attach the wire of Martin '817 in a longitudinal manner as taught by Liebig so that any twisting of the graft structure can be easily determined by viewing the marker. With this modification, the radiographic image of the radiographic indicia varies with rotational orientation of the stent.

11. **Claims 104 and 106** are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US 5,653,743; "Martin '743") in view of Martin '817, Hillstead and Cottone. Martin '743 discloses an apparatus (1) for reinforcing a bifurcated lumen comprising a proximal stent having a proximal end and a distal end, the proximal stent being expandable and having a proximal orifice at the proximal end. Martin further discloses first and second distal stents (fig. 5 shows one of them) each having a proximal and distal end (see "18" in fig. 5; col. 4, ll. 15-21 which discloses treating the internal iliac artery too, formerly known as the hypogastric artery). The proximal stent has two transversely placed portions that extend from an intermediate portion to the distal end of the proximal stent to reinforce the bifurcated lumen as shown in figure 1 (see also col. 3, ll. 4-5) . The proximal stent also has a distal orifice at the distal end of at least one of the transversely placed portions that, when expanded, receives at least one proximal end of the first and second distal stents (fig. 5). The stents are expandable and constructed of a wire

skeleton having one or more parts that extends from the respective proximal ends to the distal ends. Martin fails to disclose the claimed structure of the hoops of the stent as well as the cross-sectional area (CSA) and tapering of the proximal stent. However, Martin ‘743 does disclose that one of the transversely placed portions of the proximal stent is tapered. Martin '817 discloses a bifurcated proximal stent wherein both transversely placed portions of the proximal stent are tapered (figs 1 and 4 show this taper). Martin '817 further teaches that it is well known to provide such a distal stent with a CSA that is larger than the CSA of the portion of the proximal stent into which it fits and is thereafter expanded within in order to form an interference fit (col. 3, ll. 29-36). It would have been obvious to have incorporated these two features into the device of Martin ‘743 to ensure that the transversely placed portions of the proximal stent properly fit the smaller, branching vessels and to ensure that the distal stents that are inserted into the tapering portions of the proximal stent are interference fit therein.

12. Regarding the structure of the stents, Hillstead teaches constructing a stent such that it comprises a plurality of hoops which are axially displaced in a tubular configuration along a common axis, each of the hoops being formed by a substantially complete turn of a sinuous wire having apices and having a circumference that lies in a plane substantially perpendicular to the longitudinal axis of the stent. It would have been obvious to incorporate this stent structure into the stents of Martin in order to gain the advantages associated with this structure including a high degree of flexibility and a more direct and uniform application of expansion forces to the stent (see entire document, esp. col. 2, ll. 14-25). Hillstead fails to disclose that the apices of adjacent hoops are juxtaposed to one another and at least two juxtaposed apices are connected by a securing means. Cottone teaches providing wire hoops which are out of phase such that apices of adjacent hoops are juxtaposed to one another and are connected by a securing means (weld point 18). These securing means are advantageous because, when applied at

least to end portions of the stent, they provide anchoring portions within the stent which possess greater hoop strength than un-welded end portions, thereby making less likely unintentional movement of the stent after deployment (col. 1, ll. 20-24; col. 4, ll. 48-64). It would have been obvious to incorporate such a securing means as taught by Cottone into the device of Martin '743 in view of HIllstead so that it too may have this advantage.

13. Regarding claim 106, it would have been obvious to apply the teaching of Martin '813 regarding the distal stent having a larger CSA than the proximal stent's orifice in which it is seated to both distal stents so that they are both interference fit with the proximal stent.

14. **Claim 105** is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin '743 in view of Martin '817, Hillstead, and Cottone, as applied to claim 104 above and further in view of Chuter (US 5,562,726). Martin '743 in view of Martin '817, Hillstead, and Cottone discloses the invention substantially but does not disclose securing the proximal and distal stents with suture. However, Chuter discloses that it is well known to use suture to attach distal graft legs to a bifurcated proximal graft (see figs. 28 and 29). It would have been obvious to one skilled in the art to have further modified Martin '743 to include securing the proximal and distal stents with suture as taught by Chuter to provide additional means of preventing the stents from separating.

Response to Arguments

15. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 12/2/2010
/Kathleen Sonnett/
Examiner, Art Unit 3731